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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,677	01/03/2002	Henry Yue	PF-0590 USN	7579

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EXAMINER	
LOCKARD, JON MCCLELLAND	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,677	YUE ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,2,7,8 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-6 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XVI, claims 3-6 and 9-14 drawn to polynucleotides of SEQ ID NO:7, vectors and host cells comprising the polynucleotides of SEQ ID NO:7, and a method of recombinantly producing the polypeptide of SEQ ID NO:3, in the reply filed on 13 October 2004 is acknowledged. Applicants traverse on the grounds that the unity of invention standard must be applied in national stage applications. The Examiner agrees with this fact and would like to remind the Applicants that 371 practice for unity of invention was followed in the previous Office Action. As set forth in the previous Office Action, mailed 13 September 2004. The polypeptides of Group XV and the polynucleotides of Group XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Pursuant to 37 C.F.R. § 1.475(B-D), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, a polypeptide of SEQ ID NO:1. Groups XV and XVI do not share the same or corresponding special technical feature because the Group XV and XVI inventions are drawn patentably distinct polypeptides and nucleic acids which are structurally and functionally different chemical compounds, each of which can be made and used without the other compound. Lack of unity is shown because these compounds lack a common utility which is based upon a common technical feature which has been identified as the basis for that common utility.

2. Applicants further traverse on the ground(s) that the examination of claims to ten polynucleotide sequences does not create an undue burden. This is not found persuasive because under PCT Rule 13.2, the inventions lack the same or corresponding special technical feature for reasons set forth in the previous Office Action mailed 23 July 2004. Accordingly, U.S. restriction practice (MPEP 800) does not apply. It is further noted that due to the logarithmic increase in sequence database size, the PTO will no longer examine up to 10 sequences.

3. Applicants further traverse on the ground(s) that search of Group XV and XVI is not unduly burdensome. This is not found persuasive because under PCT Rule 13.2, the inventions lack the same or corresponding special technical feature for reasons set forth in the previous Office Action mailed 23 July 2004. Accordingly, U.S. restriction practice (MPEP 800) does not apply.

4. The restriction requirement is still deemed proper and is therefore made FINAL.

5. Claims 1-2, 7-8, and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 13 October 2004.

Status of Application, Amendments, And/Or Claims

6. Applicants' amendment filed on 13 October 2004 has been received and entered in full. Claims 1-20 are pending. Claims 3-6 and 9-14 are under consideration. All other claims are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

8. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

9. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the

date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Objections

10. Claims 3-6 and 9-14 are objected to because of the following informalities: Claims 3-6 and 9-14 encompass non-elected inventions, e.g., SEQ ID NOs:1, 2, and 4 in claim 1 and SEQ ID NOs:5, 6, and 8 in claim 9. Appropriate correction is required.

11. Claims 3-6 and 12-14 are objected to because of the following informalities: Claims 3-6 and 12-14 depend, either directly or indirectly, from a non-elected invention.

Claim Rejections - 35 USC § 101 and 35 USC §112

12. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility.

14. The instant application discloses a nucleic acid set forth as SEQ ID NO:7 that encodes the protein set forth as SEQ ID NO:3, and vectors and host cells comprising the same. The specification asserts that SEQ ID NO:3 is a member of the claudin family based on a 91% sequence identity to mouse claudin-2 (see page 9, lines 22-23; page 18, lines 25-27; Figure 2). The Specification also discloses that SEQ ID NO:7 is expressed in the various tissues including gastrointestinal, urologic, and reproductive tissues (See Table 3). However, the instant specification fails to provide any experimental data or information regarding the biological activity of the putative claudin protein set forth in SEQ ID NO:3 or encoded by the disclosed nucleic acid set forth in SEQ ID NO:7. Finally, mere homology and expression pattern is not

accepted by those of skill in the art as being predictive of function. There is no well-established utility for a specific nucleic acid or amino acid sequence and the specification fails to disclose a specific and substantial utility for the claimed invention.

15. The specification asserts the following as patentable utilities for the claimed DNA (SEQ ID NO:7) encoding the protein of SEQ ID NO:3:

1) recombinant production of the protein (pg 23, line 20 – pg 27, line 21);

2) gene therapy (pg 31, lines 27-29; pg 34, line 8 – pg 36, line 4);

3) diagnostic assays (pg 39, lines 18-23; pg 40, line 8 – pg 43, line 13);

6) as hybridization probes and PCR primers (pg 39, lines 24-34);

7) methods of monitoring treatment (pg 43, lines 14-17);

8) targets in a microarray (pg 44, lines 3-8); and

9) mapping naturally occurring genomic sequence (pg 44, line 14 – pg 45, line6).

16. These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the claimed DNA or the protein encoded by it, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, further research would be required to determine the properties of the claimed claudin nucleic acid of SEQ ID NO:7 or to identify a disease that can be treated or diagnosed with the claimed molecules, which is insufficient to meet the requirement of 35 USC § 101.

17. These activities and functions are conjectural and are based solely on the identification of the putative protein of SEQ ID NO:3 as being a claudin. While it is credible that SEQ ID NO:3 is a claudin, its identification as such is not sufficient to establish either a well known, or a

specific, substantial and credible utility. There is no ligand identified that binds to it, no signaling pathway with which it is involved, and no disease or disorder correlated with the polypeptide. The use of a putative claudin to discover its biological properties does not constitute a specific, substantial utility. Since the instant specification does not disclose how to use the polypeptide of SEQ ID NO:3, a skilled artisan would not know how to use nucleic acids of SEQ ID NO:7 that encode the polypeptide.

18. The art teaches that more than 20 different claudins have been identified, but their distributions and functions are still incompletely defined. The art further teaches copolymerization of different claudins in a single tight junction strand, suggesting that the overall tight junction barrier is defined by contributions from an ensemble of different claudins coexpressed and incorporated into the same tight junction strand (Van Itallie et al., 2003, Am. J. Renal Physiol. 285:F1078-F1084). With over 20 claudins identified thus far, the combinatorial possibilities for structure and function are very large and have yet to be elucidated (Anderson, 2001, News Physiol. Sci. 16:126-130). Thus, although the homology of the claudin family, especially in the transmembrane domain regions, allows identification of such as both claudins and as being evolutionarily related, such is not predictive of function. It is possible that, after further characterization, this protein might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease.

19. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was

potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity or significance can be attributed to the protein identified in the specification as SEQ ID NO:3 or the polynucleotide encoding it (SEQ ID NO:7), the claimed invention is incomplete.

20. Claims 3-6 and 9-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

21. Furthermore, even if the protein of SEQ ID NO:3 or the DNA of SEQ ID NO:7 that encodes SEQ ID NO:3 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention.

22. Claim 3 recites a polynucleotide encoding the polypeptide of SEQ ID NO:3 or a fragment thereof, claims 4 and 10 recite a polynucleotide variant having at least 90% sequence identity to the polynucleotide of SEQ ID NO:7 or a fragment thereof or the polynucleotide encoding the polypeptide of SEQ ID NO:3, claim 5 recites a polynucleotide that hybridizes under stringent

conditions (See 112¶2 rejection below) to the polynucleotide encoding the polypeptide of SEQ ID NO:3, and claims 9 and 12 recite a fragment of the polynucleotide of SEQ ID NO:7 or the polynucleotide encoding the polypeptide of SEQ ID NO:3. However, other than the protein of SEQ ID NO:3 and the DNA of SEQ ID NO:7 that encodes the protein, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure has not shown (1) which portions of SEQ ID NO:3 or SEQ ID NO:7 are critical to the activity of the protein of SEQ ID NO:3 (which is itself unknown); (2) what modifications (e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:3 that will result in protein mutants with the same activity as the protein of SEQ ID NO:3; and (3) any guidance on how to use peptides of SEQ ID NO:3 which would, based on the language of said claims, encompass both active and inactive variants of SEQ ID NO:3. The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions (See Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., The Protein Folding Problem and Tertiary Structure Prediction, 1994, pp. 492-495). For example, the art teaches that charged amino acid residues of the first extracellular domain of claudins determines transepithelial electrical resistance and paracellular charge selectivity, and that amino acid residue 65 has been shown to be critical for charge selectivity of claudins-4 and –15 (Colegio et al., 2003, Am. J. Cell Physiol. 284:C1346-C1354)

23. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of substitutions/deletions on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

24. Claims 3-6 and 9-14 are also rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was files, had possession of the claimed invention.

25. The specification discloses a protein of SEQ ID NO:3 and a nucleic acid sequence of SEQ ID NO:7 that encodes the protein of SEQ ID NO:3. However, claim 3 recites a polynucleotide encoding the polypeptide of SEQ ID NO:3 or a fragment thereof, claims 4 and 10 recite a polynucleotide variant having at least 90% sequence identity to the polynucleotide of SEQ ID NO:7 or a fragment thereof or the polynucleotide encoding the polypeptide of SEQ ID NO:3, claim 5 recites a polynucleotide that hybridizes under stringent conditions (See 112¶2 rejection below) to the polynucleotide encoding the polypeptide of SEQ ID NO:3, and claims 9 and 12 recite a fragment of the polynucleotide of SEQ ID NO:7 or the polynucleotide encoding the polypeptide of SEQ ID NO:3. Claim 6 depends from claim 3, claim 11 depends from claim

9, and claims 13 and 14 depend from claim 12. The claims do not require that the proteins and nucleic acids possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of DNA molecules.

26. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in claims 4 and 10 is a partial structure in the form of a recitation of percent identity. Furthermore, the only factor present in claim 5 is a mere chemical property of the DNA in the form of a recitation of hybridizes under stringent conditions to the polynucleotide encoding the polypeptide of SEQ ID NO:3. The specification does not identify any particular structure/function correlation or biological activity. The distinguishing characteristics of the claimed genus are not described. The only adequately described species is the polynucleotide set forth as SEQ ID NO:7 and the polypeptide encoded by it (SEQ ID NO:3). Accordingly, the specification does not provide adequate written description of the claimed genus.

27. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

28. With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

29. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

30. Therefore, only the polynucleotide set forth as SEQ ID NO:7 and degenerate variants thereof, and the protein encoded by it (SEQ ID NO:3), but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, 2nd paragraph

31. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

32. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

33. Claim 3 is rejected as being indefinite because claim 1, from which claim 3 depends, recites "fragments". Without knowing the minimum length of the "fragment", the metes and bounds of the claim cannot be determined.

34. Claims 4, 6, 10, and 11 are indefinite because it is not clear whether "having" means "comprises" or "consists of".

35. Claim 5 is rejected as being indefinite as there is no limiting definition of stringent hybridization conditions in the Specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which the hybridization is performed. The discussion of such at pages 20-21 of the Specification is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claim definite.

36. Claims 6 and 11 are indefinite because the metes and bounds of the term "complementary" are not clear from the prior art or the Specification. It is not clear if a full-length or partial complement is intended.

37. Claims 9 and 12 are rejected as being indefinite for reciting "fragment". Without knowing the minimum length of the "fragment", the metes and bounds of the claims cannot be determined.

38. Claim 13 is rejected as being indefinite because it is not clear whether the limitation "a

host cell" is intended to indicate an isolated or cultured host cell or a transgenic animal including a human. If a transgenic organism is intended, the claim would be subject to a 112(1) enablement rejection.

39. Claim 14 are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

40. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

41. Claims 3-6 and 9-14 are rejected under 35 U.S.C. 102(b)/(e) as being anticipated by Eaton et al. (US 2003/0119111 A1, published on 25 September 2003; priority date, 10 September 1998).

42. Eaton et al. teach a nucleic cDNA encoding a transmembrane protein with an amino acid sequence that is 100% identical to SEQ ID NO:3 of the Instant Application (See SEQ ID NO:80; Figure 80). The cDNA comprises a sequence which is 100% identical to nucleotides 1-1472 of SEQ ID NO:7 of the Instant Application that encodes the transmembrane protein (See SEQ ID

NO:79; Figure 79) and fragments thereof. Eaton et al. also teach nucleic acids that are complementary to the nucleic acid set forth as SEQ ID NO:79 and the nucleic acid encoding the polypeptide of SEQ ID NO:80, and fragments thereof (See page 2, ¶0009). This cDNA, which comprises a sequence that shares 100% sequence identity to nucleotides 1-1472 of SEQ ID NO:7 of the Instant Application, would also hybridize to SEQ ID NO:7 under stringent conditions. Eaton et al. also teach a vector and a host cell comprising the cDNA that encodes the transmembrane protein, and a method of producing the transmembrane protein (see, for example, claims 17, 19-20, and page 4, ¶0023). Thus, the reference of Eaton et al. meets all the limitations of claims 3-6 and 9-14.

Summary

43. No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
January 5, 2005

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER